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PATENT 2320-1-001PCT US

OFFICE OF PETITIONS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):

Julie R. KORENBERG et al.

SERIAL NO. :

09/720,934

EXAMINER

: N.A. Davis

FILED

January 2, 2001

ART UNIT

: 1642

FOR

ISOLATED SH3 GENES ASSOCIATED WITH

MYELOPROLIFERATIVE DISORDER AND LEUKEMIA, AND

USES THEREOF

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231 on September 27, 2002.

<u>David A. Jackson, Reg. No 26,742</u> (Name of Registered Representative)

(Signature and Date)

RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. §121

ASSISTANT COMMISSIONER FOR PATENTS WASHINGTON, D.C. 20231

Dear Sir:

Responsive to the Office Action dated March 27, 2002, issued in connection with the above-identified Application, please consider the following remarks.

This is in response to a Requirement for Restriction mailed March 27, 2002, requiring Applicant to elect between the following groups of claims for further prosecution:

Group I - Claims 1-31 and 51, drawn to a nucleic acid, oligonucleotide, vector, host vector system, pharmaceutical composition and a method of making a polypeptide.

Group II - Claims 32-34, drawn to polypeptide.

Group III - Claims 35-36, drawn to an antibody.

- Group IV Claims 37-39, drawn to a method of determining a mutation in the SH3D1A gene of a patient.
- Group V Claim 40, drawn to a method of determining whether a subject has a megakaryocytic abnormality or disorder using an antibody.
- Group VI Claims 41-44 and 50, drawn to a method of determining whether a subject has a megakaryocytic abnormality or disorder using a nucleic acid.
- Group VII Claims 45 and 48, drawn to a method of suppressing cells and identifying an agent capable of suppressing cells.
- Group VIII Claim 46, drawn to a method of screening for a somatic alteration in an SH3D1A gene by comparing DNA.
- Group IX Claim 47, drawn to a method of screening for a somatic alteration in an SH3D1A gene by comparing polypeptides.
- Group X Claim 4, drawn to a method of monitoring treatment by comparing nucleic acids at various stages.
 - Group XI Claims 52-56, drawn to a method of treatment with a nucleic acid.
- Group XII Claim 57 (sic), drawn to a transgenic nonhuman mammal comprising the SH3D1A.

In accordance with 35 U.S.C. §§121 and 372, Applicants hereby elect to prosecute the claims of Group I, drawn to a nucleic acid, oligonucleotide, vector, host vector system, pharmaceutical composition and a method of making a polypeptide, with traversal.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one application may ... be restricted to one of the inventions." Inventions are "`independent" if

"there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, and are patentable over each other" (MPEP 802.01). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

- 1. Separate classification
- 2. Separate status in the art; or
- 3. Different field of search.

Under Patent Office examining procedures, "If the search and examination of an entire application can be made without serious burden, the Examiner is encouraged to examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988).

In the present instance, the requirement as set forth is incomplete and applicants cannot determine the nature of the distinctions set forth by the examiner so that a complete and reasoned response can be presented. To this extent the election provided above is presented on applicants' best understanding of the bases for separation of the claims. No classification is given and certain of the stated groups would be clearly combinable with each other if the presumed scope of each group could be confirmed.

Specifically, the methods of Groups IV-VI could and/or do involve the same or similar steps. Further, the methods of Groups VIII-X could be practiced by the methods of Groups IV-VI as well. The possibility that these various methods could be subsumed within the claims presumed to be the subject of separately classifiable inventions illustrates the lack of

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clarity of the present requirement, and the consequent inability of the applicants to make a meaningful election. On this basis, applicants request that the examiner reconsider and withdraw the present requirement and if appropriate, issue a further requirement so that applicants will have the ability to make a proper decision for the further prosecution of the claimed subject matter of the present invention. For this reason, Applicants traverse the outstanding requirement and request its withdrawal.

For the above reasons, Applicants request withdrawal of the Requirement for Restriction, and early action on the merits as to all of the claims presently pending in the case.

In view of the above, early action on the merits is courteously solicited.

Respectfully submitted,

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